



Drug Enforcement Administration

[Docket No. DEA-987]

Bulk Manufacturer of Controlled Substances Application: Patheon API

Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 2, 2022, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605-5420, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-Dimethyltryptamine	7431	I
Alpha-Methyltryptamine	7432	I
Dimethyltryptamine	7435	I
Psilocybin	7437	I
Psilocyn	7438	I
Thebaine	9333	II
Oxymorphone	9652	II
Noroxymorphone	9668	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture this drug as synthetic. No other activities for these drug codes are authorized for this registration.

Matthew J. Strait,
Deputy Assistant Administrator.